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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification Objection

1. Claim 7 is objected to for the following informalities: Claim 7 requires a period (.) at the end of the sentence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 102(a) as anticipated by Gladstone et al, *(Seminars in Neurology, 2003 , 23.3, p. 265-275).*

Claims 1-5 and 7-9 are drawn to a method for treating an acute pain medication overuse disorder, the method comprising a step of local administration of a botulinum toxin to a patient with acute pain medication overuse disorder, thereby treating the acute pain medication overuse disorder.

Gladstone et al teach a method of treating patients with medication overuse disorder and chronic headache with botulinum toxin (pages 271-272). Gladstone et al teach that the risk factors for development of chronic daily headache include medication overuse (Table 2, page 271). Gladstone et al teach that botulinum toxin (BoNT) has been used to treat migraine and other headache types. Gladstone et al teach that botulinum toxin A is administered with at fixed injection sites, at sites of pain or

tenderness or at a combination of both (page 272). Gladstone et al teach that the dose of BoNT used for migraine is between 25 and 100 units (page 272).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-9 are rejected under 35 U.S.C. 103(a) as unpatentable over Katsarava et al *(Neurology, May 27, 2003, Vol., 60, No. 10, pp. 1682-183)* in view of Aoki (*U.S. Patent No. 6 458, 365 published October 1, 2002)*

Katsarava et al teach a study of 98 patients that have medication overuse headaches (see Title and the Abstract). Katsarava et al teach that 71% of the patients had migraine headaches, 14% of the patients had tension-type headaches and 15% had chronic headaches (page 1682). Katsarava et al teach that the study was designed

so that patient would withdraw from taking "headache medications"(page 1682). Katsarava et al teach that medication withdrawal relapse rate for patients was 38%. Katsarava et al teach that two predictors for relapse found during the study were type of primary headache and type of overused headache medication (page 1683). Katsarava et al teach that the relapse was lower for patients that suffered from migraine headaches than patients that suffered from tension-type headaches or a combination of migraine and tension-type headaches (see the Abstract).

Katsarava et al do not teach the use of botulinum toxin to treat headaches and headache related symptoms.

Aoki et al teach a method of treating a tension headache by intramuscular or subcutaneous administration of botulinum toxin to the head or neck location of a patient, thereby relieving tension headache pain (columns 9-10). Aoki et al teach that botulinum toxins types A-G can be used in the invention (see the Abstract). Aoki et al teach that dosages of botulinum toxin used in the invention range from about 0.01 units to about 1000 units (column 4). Aoki et al teach that botulinum toxin can be administered to the facial muscles of a patient (column 1, Example 1).

It would be *prima facie* obvious at the time the invention was made to use botulinum toxin to treat patients that have medication overuse disorder because Katsarava et al teach that medication overuse disorder is associated with patients that have migraine and tension-type headaches and medication withdrawal relapse is more likely to occur in patients that have tension-type headaches. Aoki teach that botulinum toxin can be used to treat patients that suffer from tension-type headaches. One would

be motivated to administer botulinum toxin to a patient suffering from medication overuse disorder and chronic headaches since botulinum toxin has been shown to treat patients with headaches, especially tension-type headaches. It would be expected barring evidence to the contrary, that the administration of botulinum toxin to a patient suffering from medication overuse disorder would be effective in preventing the patient against medication withdrawal relapse.

Pertinent Art

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (Eross, *Neurology, May 27, 2003, 60(10), E8-9*)

5. No claims are allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
September 13, 2004

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